



## Form PTO-1449 Substitute

Applicant(s): Velayudhan Sahadevan

Filing Date: February 27, 2002, "Hormonal Implant Treatment of Breast Cancer"

### U.S. Patent Documents

Ref.	Number	Issue Date	Name(s)	Class	Subclass	Filing Date
(16)	4,321,208	03/23/1982	Sahadevan, V.	552/627;	552/544	09/27/1976
(18)	4,389,330	06/21/1983	Tice; Thomas R.	427/213.36;	264/4.1	10/06/1980
(19)	5,340,586	08/23/1994	Pike; Malcolm C.; S	424/426;	424/43	05/17/1993
(20)	4,244,949	01/13/1981	Gupta; Gopi N.	514/178;	A61K 031/56	04/06/1978
(21)	5,340,585	08/23/1994	Pike, Malcolm C.,	424/426;	424/42	05/17/1993
(22)	4,210,644	07/01/1980	Ewing; Larry L.; D	514/170;	514/84	02/23/1978

### Foreign Patent Documents

Initial	Number	Issue Date	Country	Class	Subclass	Translated
---------	--------	------------	---------	-------	----------	------------

### Reference # and Other Prior Art

Ref. (Including Authors, Title, Date, Pertinent Pages, Etc.)

1. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1656-; Ref. # 110: Early Breast Cancer Trialists's Collaborative Group. Tamoxifen for early breast cancer: an overview of the randomized trials. Lancet 1998; 352:930.
2. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1656-; Ref.#111: Nayfield

SG, Karp JE, Ford LG, Dorr FA, Kramer FS. Potential role of tamoxifen in prevention of breast cancer. J Natl Cancer Inst 1991;83:1450.

3. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1656-; Ref. # 112: Radmacher MD, Simon R. Estimation of tamoxifen's efficacy for preventing the formation and growth of breast tumors. J Natl Cancer Inst 2000;92:48.
4. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1656-; Ref. #118: Ettinger B, Black DM, Mitlak BH, et al. Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: results from a 3-year randomized clinical trial. Multiple Outcomes of Raloxifene Evaluation (MORE) Investigators. JAMA 1999;282:637.
5. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1656-; Ref. # 119: Cummings SR, Eckert S, Krueger KA, et al. The effect of raloxifene on risk of breast cancer in postmenopausal women: results from the MORE randomized trial. JAMA 1999;281:2189.

- CA
6. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1690, Table 37.2-20
  7. Erlichman C, and Loprinzi CL, Hormonal Therapies, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 479-80, Ref # 61, Hayes DF, Vanzyl JA, Hacking A, et al, Randomized comparison of tamoxifen and two separate doses of toremifene in postmenopausal patients with metastatic breast cancer, J Clin Oncol 1995; 13: 2556.
  8. Erlichman C, and Loprinzi CL, Hormonal Therapies, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 480.
  9. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1691, Ref, # 113, Fisher B, Costantino JP, Wickerham DL, et.al: Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. J Natl Cancer Inst 1998; 90:1371.
  - OK 10. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S.

and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1657-; Ref. # 113: Fisher B, Costantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. J Natl Cancer Inst 1998;90:1371.

11. Winer E. P., Morrow M., Osborne C. K., and Harris J. R., Malignant Tumors of the Breast, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 1657-; Ref. # 114: Day R, Ganz PA, Costantino JP. Health-related quality of life and tamoxifen in breast cancer prevention: a report from the National Surgical Adjuvant Breast and Bowel Project P-1 Study. J Clin Oncol 1999;17:2659.

12. Haller DG, Fox KR, Schuchter LM, Metastatic Breast Cancer; In Breast Cancer Treatment A Comprehensive Guide to Management; Fowble B, Goodman RL, Glick JH and Rosato EF (Ed), Mosby Year Book, 1991, page 413.

13. Nolvadex, tamoxifen citrate, Zeneca Pharmaceuticals, Physicians Desk Reference, PDR 51, 1997; p 2957

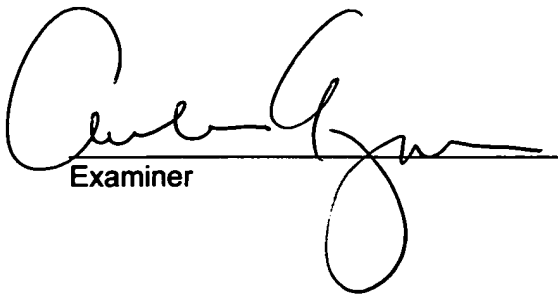
14. Erlichman C, and Loprinzi CL, Hormonal Therapies, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 479, Ref # 52, Daniel CP, Gaskell SJ, Bishop H, et al

Determination of tamoxifen and biologically active metabolites in human breast tumors and plasma, Eur J Cancer Clin Oncol 1981; 17: p 1183.

15. Erlichman C, and Loprinzi CL, Hormonal Therapies, In Cancer, Principles and Practice of Oncology, 6<sup>th</sup> edition, Vol. 1; DeVita, Jr., Hellman S. and Rosenberg (Ed), Lippincott Williams & Wilkins, 2001 page 479.
16. Sahadevan V: Preparation of directly iodinated steroid hormones and related compounds, US Patent 4,321,208; 1982.
17. Pharmacia and Upjohn Company, Depo-Provera, Physicians Desk Reference, PDR, 51,1997, p2079.
18. Tice TR, and Lewis DH: Microencapsulation process, US Patent 4,389,330; 1983.
19. Pike M and Spicer DV: Methods and formulations for use in treating oophorectomized women, US Patent 5,340,586; 1994.
20. Gupta GN: Manufacture of long term contraceptive implant, US Patent 4,244,949; 1981.
21. Pike M and Spicer DV: Methods and formulations for use in treating benign gynecological disorders; US Patent 5,340,585; 1994.
22. Ewing LL, Desjardins C: Male contraception; US Patent 4,210,644; 1980.

23. Norplant System, Wyeth Ayerst Laboratories, Physicians Desk Reference, PDR, 51, 1997,

p2868

  
Examiner

9/30/03  
Date Considered